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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/524,793 | 10/20/2005 | Kenneth M. Evans | XY-Hypodermic-USNP | 8305 |
| 33549 | 7590 | 10/29/2008 | | |
| SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521 | | | EXAMINER FRITCHMAN, REBECCA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1797 | |
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| | | | 10/29/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/524,793 | Applicant(s) EVANS, KENNETH M. | |
| | Examiner REBECCA FRITCHMAN | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/15/2005, 02/28/2006, 06/08/2006, 08/15/2006,</u> | 6) <input type="checkbox"/> Other: _____ |
| <u>02/26/2007, 06/12/2008</u> | |

***Detailed Action
Summary***

1. This is the initial Office action based on the 11/222335 application filed on 09/08/2005.
2. Claims 1-17 are pending and have been fully considered.

Election/Restrictions

3. Restriction to one of the following inventions is required under U.S.C. 121:
 - I. Claims 1-14, & 56-69 drawn to a method of flow cytometry, classified in class 436, subclass 63.
 - II. Claims 15-22, & 24-25 drawn to a flow cytometer apparatus, classified in class 436, subclass 63.

4. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method can be practiced by an apparatus without a nozzle, particle injector, or selectably variable adjustment element.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be

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maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. During a telephone conversation with Nicole Ressue on 10/07/2008 a provisional election was made without traverse to prosecute the invention of 10/524793 claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(e) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that

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an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-6, & 9-14 are rejected under 35 U.S.C. 102(e) as being unpatentable over BUCHANAN in US 6604435.

With respect to Claim 1, BUCHANAN et al. teaches of a method of flow cytometry which focuses on sorting delicate cells, especially living sperm cells(which are obviously from male species of mammals)(column 1, lines 11-18). BUCHANAN et al. also teach injecting fluid into a ribbon flow through an injection point (column 8, line 62-67 & column 9, lines 1-9). In addition to that, BUCHANAN et al also teaches of a liquid flow cytometer system where a sample is processed into individual droplets prior to being analyzed and sorted (column 5, lines 26-31). Also, BUCHANAN et al. teach of sorting sperm containing drops by the sorting device(obviously two or more groups)(column 10, lines 33-37) and of the possibility of adjusting the injection point(from 6mm to 10 mm or greater)(column 9, lines 1-32).

With respect to Claim 2, BUCHANAN et al. teaches of the use of bovine and equine sperm cells which have been stained and sorted by their DNA content (column 15, lines 5-10).

With respect to Claim 3, BUCHANAN et al. teaches of the sample stream being drawn into a thin ribbon by the sheath fluid (column 6, lines 36-37).

With respect to Claim 4, BUCHANAN et al. teaches of sperm cells being buffered in specifically prepared sperm compatible buffer (column 10, lines 41-

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44). Citrate, phosphate, and HEPES buffer are all well known in the art and would have been obvious to use.

With respect to Claim 5, BUCHANAN et al. teaches of obtaining sperm cells of the male and female bovine and equine species wherein the step of injecting sperm cells into the sheath fluid comprises injecting sperm cells from the selected groups into the sheath fluid at an injection point (Claim 10 & 17). It is inherent to inject the sperm cells of the first and second species at different injection points.

With respect to Claim 6, BUCHANAN et al. teach of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees(column 6, lines 40-67, column 7, lines 1-27).

With respect to Claim 9, BUCHANAN et al. teaches of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teaches of varying the size of the nozzle, height and the diameter(column 7, lines 9-15) through which the distance between injection points of the sperm cells into the fluid stream would be altered.

With respect to Claim 10, BUCHANAN et al. teaches of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees(4 degrees is the optimum for preferred stream resolution)(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teaches of varying the size of the nozzle, height and the diameter (column 7, lines 9-15) through

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which the distance between injection point of the sperm cells into the fluid stream would be altered.

With respect to Claim 11, BUCHANAN et al. teach of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees(4 degrees is the optimum for preferred stream resolution)(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teach of the sample stream being drawn into a thin ribbon(due to the beveling) by the sheath fluid, the resulting change in flow condition causing a corresponding orientation of the sample material (column 6, lines 35-39).

With respect to Claim 12, BUCHANAN et al. teach of et al. teach of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees(4 degrees is the optimum for preferred stream resolution)(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teach of the sample stream being drawn into a thin ribbon(due to the beveling) by the sheath fluid, the resulting change in flow condition causing a corresponding orientation of the sample material (column 6, lines 35-39).

With respect to Claim 13, BUCHANAN et al. teaches of sorting delicate cells, especially sperm cells (column 1, lines 16-17).

With respect to Claim 14, BUCHANAN et al. teaches of sorting delicate cells, especially sperm cells (column 1, lines 16-17). BUCHANAN et al. also teaches of the sperm containing drops being sorted by the sorting device and collected by the sperm-compatible collecting system wherein the X or Y chromosome bearing sperm may be used for insemination(column 10, lines 50-57).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 7 & 8 are rejected under 35 U.S.C. 103(a) as being obvious over BUCHANAN in US 6604435 and in further view of NEWTON in US 6230982.

BUCHANAN et al. teach of a low acceleration method of flow cytometry. BUCHANAN et al. do not teach of the slidable adjustment of a slidly adjustable coupling between the particle injector and the nozzle body part.

With respect to Claim 7, NEWTON teaches of an adjustable valve for varying the position of injection into a flowing liquid stream, slidably adjusting the position of the valve with respect to the center of the stream (Claim 29). It would have been obvious to modify the method of flow cytometry of BUCHANAN by using the adjustable, slidable fluid dispensing vale of NEWTON in order to adjust the inlet of the cells within the carrier fluid to minimize backflow which results in unwanted contamination of dispersing fluids (NEWTON, column 1, lines 19-23).

With respect to Claim 7, NEWTON teaches of slidably adjusting the position of the valve with respect to the center of the stream (Claim 29).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.F.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797